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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,365	01/18/2002	Mayumi Kotani	SAEGU92.001APC	7977

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,365	KOTANI ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10-22 and 24-42* is/are pending in the application.

4a) Of the above claim(s) *2-9 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-22 and 24-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on January 29, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-22, 25-30 and 37-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a composition and method for the prevention and/or treatment of type I allergies. **Claims 1, 10-22, 25-30 and 37-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of type I allergies ", does not reasonably provide enablement for "prevention of type I allergies". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.**

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors

have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to the method of treating or preventing type I allergies in a subject with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses anticipating the location of the allergy, how different allergies will react to the allergy inhibition, how different allergies will be effected, how skin allergies will be treated in the same manner as bronchial allergies and subsequently administering instant composition such that the subject treated will not have adverse side effects or no effects at all.

Breadth of Claims: The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claim encompasses prevention of multiple complex allergies in which all type I allergies are prevented since the disease may be caused and treated by other means. This may or may not be addressed by the administration of the composition.

State of the Art: The state of the art does not recognize the administration of astragalin to prevent type I allergies. The state of the art recognizes the treatment of the symptoms of these allergies but not the cure of the allergies.

Guidance of the Specification: The guidance given by the specification on how to anticipate type I allergies and their location to prevent the allergies is absent.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to completely envisioning/anticipating type I allergies and preventing type I allergies in a human subject with the administration of the instant

composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

The Amount of Experimentation Necessary: In order to practice claimed invention, one of ordinary skill in the art would have to first to anticipate type I allergies, their location, the effective dosage, duration of treatment, etc. to determine whether or not the instant composition prevents the allergies. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until invention was shown to be successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

For these reasons the claim is rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-30 and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New Claims 25 –30 are drawn to a method of preventing pollinosis by administering a composition to a subject *who previously experienced pollinois*. It is unclear to the Examiner how one could prevent pollinosis in someone who already suffers from the condition.

New Claims 37-42 are drawn to a method of preventing atopic dermatitis by administering a composition to a subject who already suffers from atopic dermatitis. Again, it is unclear to the Examiner how one could prevent a condition in someone who already suffers from the same condition (atopic dermatitis).

Appropriate clarification is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10-22 and 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over H. Fukumoto et al., Anti-anaphylactic Effects of the Principal Compounds from the White Petals of Impatiens balsamina L., Phytotherapy Research, Vol. 10, 1996, pp.202-206 in combination with Sawruk (US 5478579).

Fukumoto teaches kaempferol-3-glucoside is known as an anti-anaphylactic agent (See entire document). Further, the compounds taken from white petals of

Impatiens balsamina L. inhibit IgE-mediated anaphylaxis (See Introduction). The compounds extracted were used to treat allergic reactions on skin (See entire document). Fukumoto further teaches that astragalin is known to inhibit the release of IgE-promoted histamines (Page 205, second column). Fukumoto does not expressly teach pharmaceutical compositions for the compounds extracted.

Sawruk teaches flavonol aglycone glycosides in pharmaceutical formulations (Col. 2, lines 1-17). One such compound is astragalin (Col. 2, lines 53-62). The dosage for the compounds is 50-250 mg/daily dose but will vary depending on age weight, health and sex of the patient and can be administered 2 to 3 times a day (Col. 4, lines 1-14). The compounds can be formulated in various pharmaceutical compositions with conventional pharmaceutical excipients (Col. 4, lines 15-43). Sawruk does not expressly teach the same exact concentration ranges of the astragalin but does teach a range that overlaps and/or encompasses the ranges recited in the instant claims. It is the position of the Examiner that the prior art teaches oral compositions and no criticality is seen in the composition being a food product.

With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a pharmaceutical formulation comprising astragalin that can be used to treat allergies, specifically conditions that are related to IgE promoted histamines levels.

One of ordinary skill in the art would have been motivated to do this to deliver the active compound in a manner that will best achieve the result of alleviating the allergic reactions.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed January 29, 2004 have been fully considered but they are not persuasive. Applicants argue that the prior art teaches astragalin to be used as an antianaphylactic composition, which is different from the atopic dermatitis and pollinosis conditions that are currently claimed. Further, applicants argue that the instant claims are enabled from methods of *preventing* pollinosis and atopic dermatitis by reference to the Examples recited in the Specification.

To respond to the latter argument first, it is the position of the Examiner that the subjects or mice of the experiments referenced in the Specification either already suffered from the condition (pollinosis) or were bred to manifest the condition (atopic dermatitis). Therefore, it is unclear how one can prevent a condition in a subject when the subject already suffered from the condition. It is the position of the Examiner that this is indicative of a treatment method but not a preventative method. Therefore, the enablement rejection is maintained.

As for the arguments with regard to the art cited, it is the position of the Examiner that the prior art teaches a compound that is known to inhibit IgE-promoted histamine. Applicants admit in their specification that the conditions recited in the instant claims are

a result of raised levels of IgE in serum. Therefore, it would be obvious to one of ordinary skill in the art that by inhibiting IgE you are in turn treating the conditions related to raised levels of IgE, i.e., pollinosis and atopic dermatitis. The obviousness rejections are therefore maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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